

REMARKS

Applicants thank the Examiner for the courtesy of the January 17, 2012 telephone interview. The substance of the interview is summarized in the below remarks.

Objections to the Specification

The specification was objected to as failing to provide proper antecedent basis for the claimed subject matter. During the interview, the Examiner explained that new claims 41-49 submitted in the October 18, 2011 Amendment had proper support, however, the specification did not have specifically corresponding language. Applicant respectfully submits that the specification is herein amended to provide proper antecedent basis for the claimed subject matter. No new matter is added. Withdrawal of this objection is respectfully requested.

Claim Rejections Under 35 U.S.C. § 103

Claims 41, 42 and 44-49 stand rejected under 35 U.S.C. 103(a) as unpatentable over U.S. Patent No. 5,947,953 (Ash et al.) in view of U.S. Patent No. 4,405,313 (Sisley et al.) further in view of either U.S. Patent No. 4,037,599 (Raulerson) or U.S. Appln. Publication No. 2002/0120224 (Zia et al.). Claim 43 stands rejected under 35 U.S.C. 103(a) as unpatentable over Ash et al. in view of Sisley et al. and either Raulerson or Zia et al. and further in view of U.S. Patent No. 5,800,414 (Cazal). Applicant traverses these rejections.

“To establish a prima facie case of obviousness, ... the prior art reference (or references when combined) must teach or suggest all the claim limitations.” M.P.E.P. §2143. Additionally, as set forth by the Supreme Court in *KSR Int'l Co. v. Teleflex, Inc.*, No. 04-1350 (U.S. Apr. 30, 2007), it is necessary to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the prior art elements in the manner claimed.

Independent claim 41 recites “[a] multiple catheter assembly, comprising: a first flexible catheter having a first distal end configured for implantation into a patient and a first proximal end configured for attachment to a first medical element; a second flexible catheter having a second distal end configured for implantation into a patient and a second proximal end configured for attachment to a second medical element, the first and second flexible catheters attached to one another via a splittable bond extending from a bond distal end to a bond proximal

end, the bond proximal end initially spaced a first initial distance from the first proximal end and a second initial distance from the second proximal end, wherein the distances from the proximal ends of first and second flexible catheters to the bond proximal end may be increased by splitting the splittable bond; and a hub member defining a distal passage configured to receive the attached first and second flexible catheters and first and second proximal passages intersecting the distal passage at an intersection, the first proximal passage configured for passage of the first flexible catheter and having a length less than the first initial distance such that the first flexible catheter extends from a first proximal opening of the hub member, the second proximal passage configured for passage of the second flexible catheter and having a length less than the second initial distance such that the second flexible catheter extends from a second proximal opening of the hub member, wherein the hub member is configured such that the hub member is longitudinally adjustable along the flexible catheters to position the bond proximal end proximate to the hub member intersection.”

As explained in paragraph [0008], “the surgeon may desire or require a different length of a subcutaneous tunnel for a different patient. However, the location of the catheter hub may dictate the length and/or location of the subcutaneous tunnel. It would be beneficial to provide a catheter assembly that has an adjustable location for the hub along the catheter assembly to provide the surgeon options for securing the catheter assembly to the patient.” The presently claimed invention allows the location of the hub and the configuration of the flexible catheters to be adjusted to facilitate a desired positioning of the hub.

None of the cited references, alone or in any reasonable combination, teach or suggest splittable flexible catheters with a hub member having a split passage which is longitudinally adjustable along the catheters to position the bond proximal end proximate to the hub member intersection.

The Final Office Action cites to Ash et al. as teaching a hub and to Sisley et al. for the general proposition of catheters extending through a hub. The Final Office Action cites to Raulerson and Zia et al. as teaching tubing apparatus that may be opened and therefore concludes that the combined structure of Ash et al. and Sisley et al. may be adjustable. Applicant respectfully submits that such a combination overlooks the teaching of the prior art away from such a combination.

As explained during the interview, Ash et al., which was filed after the issuance of Sisley et al., specifically teaches an assembly wherein the hub 24 forms a part of the passage between the catheters and the extension tubes. More specifically, Ash et al. explains at column 12, lines 15-32 that

As discussed above, the cannulating portion 20 of the assembly 10 is preferably joined to the extension tube portion 22 in the hub 24. As shown in FIGS. 1 and 2, the extension tube portion 22 includes a first extension tube 84 having a distal end 86 and a proximal end 88, and a second extension tube 90 having a distal end 92 and a proximal end 94. The proximal ends 88, 94 are shown in FIG. 1, and the distal ends 86, 92 are shown in FIG. 2. **The extension tube distal ends 86, 92 and the respective proximal openings 78, 82 of the catheters 26, 30 are brought into fluid communication with each other via tunnels 116, 118 molded in the hub 24.** The extension tube proximal ends 88, 94 are preferably connected to respective female luer locks 96, 98 in a conventional manner. If desired, the female luer locks 96, 98 may be substituted with any suitable type of quick connect fittings, ferrule connectors, threadable connector, and the like.

(emphasis added). Ash et al. teaches that tunnels molded into the hub provide fluid communication between the catheters and the extension tubes. Raulerson teaches a similar structure wherein hub conduit portions 25 and 27 provide fluid communication between the catheter 14 and the fluid conduits 44 and 46. (See Fig. 2 of Raulerson). For the devices of Ash et al. and Raulerson to function properly, the ends of the catheters must be fixed within the hub.

One skilled in the art would not simply overlook the teachings of Ash et al. and Raulerson, i.e. to fix the catheter ends within the hub and use the hub portions as fluid conduits, and instead pass the catheters completely through the hub 24 as suggested in the Office Action. As set forth in M.P.E.P. 2141.02 VI, “[a] prior art reference must be considered in its entirety, i.e. as a whole, including portions that would lead away from the claimed invention.” (citations omitted).

Furthermore, as explained during the interview, Sisley et al. also teaches away from the claimed invention. As set forth at column 5, lines 31-35, Sisley et al. teaches a splitter 22 which wraps the junction of the tubes 12 and 14 and which eliminates further splitting of the tubes 12 and 14. The splitter 22 is fixed in position and is not intended to be adjustable, but instead is intended to fix the split relationship of the tubes. Furthermore, Sisley et al. is not concerned with splitting the tubes, but instead teaches the figure-8 configuration to increase flexibility of the dual lumen and to reduce the amount of material used. Sisley et al. explains that the second fill-

in portion thereof can extend over substantially the entire remaining length of the catheter. (See column 4, lines 15-39).

Zia et al. and Raulerson are cited for teaching hinged hub assemblies, however, neither of these references teach hub assemblies having a split passage which is longitudinally adjustable along the catheters to position the bond proximal end proximate to the hub member intersection and to have proximal passage lengths less than the lengths of the proximal portions of the flexible catheters such that the flexible catheters extend from respective openings in the hub. The device of Zia et al. is simply a tube holder to prevent kinking and to facilitate transport or support. A singular tube runs through the housing of Zia et al. and there is no teaching of splitting or adjusting the housing relative to a bonded portion of the catheters. Raulerson teaches a housing in which the catheter tubes terminate and provides fixed locations for the catheter tube ends.

Ash et al. and Raulerson both teach a device wherein the catheter ends must be fixed within a hub which defines portions of the fluid channels and Sisley et al. teaches a device wherein a splitter is wrapped about the junction of the tubes to eliminate further splitting of the tubes. Zia et al. teaches a tubing apparatus for a single tube and does not provide any teaching of an adjustable hub along a splittable catheter. The cited references teach away from the claimed invention and there is no reasonable basis to combine the references as suggested in the Final Office Action.

The remaining references are cited for limited teachings and do not overcome the shortcomings of Ash et al., Sisley et al., Zia et al. and Raulerson. It is respectfully submitted that independent claim 41 is in condition for allowance. Claims 42-49 each depend from claim 41 and are allowable for at least the reasons set forth above.

It is respectfully submitted that each of the pending claims is in condition for allowance. Early reconsideration and allowance of each of the pending claims are respectfully requested.

If the Examiner believes an interview, either personal or telephonic, will advance the prosecution of this matter, the Examiner is invited to contact the undersigned to arrange the same.

Respectfully Submitted,

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Date

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